REMARKS

Claims 8, 13, 32, 37, 41, and 49-51 have been hereinabove amended. Claims 10-11, 14, 34-35, 38 and 46 have been canceled without prejudice. New claims 52-53 have been added. Claims 8, 12-13, 15-16, 32, 36-37, 39-41, and 49-53 are now pending for the Examiner's consideration.

Support for the amendments are as follows:

Amended Claim	Support
Claim 8	Original claim 10
Claims 13 and 37	Example 2, specification as filed page 20, lines 16-17 and 22-23
Claim 32	Original claims 34 and 46
Claim 41	Claim dependency was amended to include the limitation of original claim 36
Claim 49	Claim dependency was amended to include the limitation of original claim 46; Specification as filed page 2, lines 30-34
Claim 50	Claim dependency was amended to include the limitation of original claim 46; Specification as filed page 2, lines 30-34
Claim 51	Claim dependency was amended to include the limitation of original claim 46; Specification as filed page 2, lines 30-34
Claim 52	Original claim 46; Specification as filed page 2, lines 30-34; Page 4, line 2; and Example 2, page 20, line 6
Claim 53	Original claim 46; Specification as filed page 2, lines 30-34; Page 4, line 2; and Example 2, page 20, line 6

No new matter is added.

Applicants request reconsideration of the pending claims in light of the preceding amendments and following remarks.

Claim objection

Claim 32 was objected for the abbreviated terms "VEGF", "PDGF", and "c-KIT". Applicants submit that those skilled in the art understand these terms as can be searched in any publicly available encyclopedia or dictionary, for example, Wikipedia encyclopedia. However, to expedite prosecution and to place the claim in the condition for allowance, Claim 32 has been amended in that the objected terms have now been deleted. In light of the amendment, the objection to claim 32 is now moot.

35 U.S.C. §112

Claims 32-41 were rejected under 35 U.S.C. §112, 1st paragraph, for the reasons set forth on pages 2-4 of the Office Action. To expedite prosecution and to place the claim in the condition for allowance, Claim 32 has been amended to recite methods of treating specific types of cancer as recited in original claim 46. Claims 33-35 and 38 were canceled, thus the rejections of these claims are deemed moot. Claims 36-37, 39-41 are dependent from claim 32 and therefore have the cancer limitation as amended.

Applicants believe the rejection does not apply to the claims as now presented and respectfully request that it be reconsidered and withdrawn.

35 U.S.C. §102 (b)

Claims 8-16 were rejected under 35 U.S.C. §102(b) as being anticipated by Kania et al. (WO 2001/02369, now US Patent No. 6,531,491), for the reasons set forth on pages 4-5 of the Office Action. Applicants respectfully traverse.

With regard to claims 8-16, independent claim 8 as amended recites a dosage form comprising an amount of 1-20 mg of the compound of formula 1. To expedite prosecution, claims 9-11 and 14 were canceled, thus the rejections of these claims are moot. The remaining claims 12-13 and 15-16 depend from claim 8, thus the following arguments apply. Applicants submit that Kania discloses a generic range of 0.001 to 50 mg/kg, corresponding to 0.07 to 3500 mg for a 70 kg mammal. This disclosed range spans more than four orders of magnitude, and is approximately 15 times less at the lower end, and 175 times greater at the upper end, than the presently claimed dosage range of 1 to 20 mg. It is well-established that disclosure of a broad numerical range does not anticipate a later, more narrow range falling within the broader range; see MPEP 2131.03, citing Atofina v. Great Lakes Chem. Corp, 441 F.3d 991 (Fed. Cir. 2006), wherein a prior art range of 100-500 ºC did not describe a claimed range of 330-450 ºC with sufficient specificity to be anticipatory. Nowhere in Kania the presently claimed range of 1 to 20 mg dosage is taught. Clearly the broad disclosure of Kania does not anticipate the narrow range now specifically claimed.

Applicants respectfully request that the anticipation rejection of claims 8, 12-13 and 15-16 over Kania be withdrawn.

Claims 32-41 and 46 were rejected under 35 U.S.C. §102(b) as being anticipated by Kania et al. (WO 2001/02369, now US Patent No. 6,531,491), for the reasons set forth on pages 5-7 of the Office Action. Applicants respectfully traverse.

With regard to claims 32-41 and 46, claim 32 has been amended to recite the specific cancers, and the dosage amount of the compound of formula I is from 1 to 20 mg. To expedite prosecution, claims 33-35, 38, and 46 were canceled, thus the rejections of these claims are

moot. The remaining claims 36-37 and 39-41 depend from claim 32, thus the following arguments apply. Nowhere in Kania the claimed range of 1 to 20 mg dosage is taught, thus clearly Kania does not anticipate claims 32, 36-37 and 39-41.

Applicants respectfully request that the anticipation rejection of claims 32, 36-37 and 39-41 over Kania be withdrawn.

35 U.S.C. § 103

Applicants are grateful to the Examiner that the obviousness rejections have been withdrawn.

Double Patenting

Claims 8-16, 32-41, 46, and 49-51 were rejected under the judicially-created doctrine of obviousness-type double patenting over claims 1-11 of U.S. Patent No. 7,141,581, for the reasons set forth on pages 7-8 of the Office Action. Applicants respectfully traverse.

Nevertheless, to expedite prosecution, claims 9-11, 14, 33-35, 38, and 46 were cancelled, thus the rejections over these claims are moot. The remaining claims 8, 12-13, 15-16, 32, 36-37, and 39-41 have been hereinabove amended to recite still narrower dosage ranges and Applicants submit the following arguments. The claims of the '581 patent are directed to methods of treatment with various compounds and without any specific dosing ranges. Nothing in the claims of the '581 patent teaches or suggests any dosing range, much less the amended range of 1 to 20 mg, nor using the specific range of 1 to 20 mg of the presently recited single compound of formula I. For the same reasons as discussed above, claims 8, 12-13, 15-16, 32, 36-37, and 39-41 are not rendered obvious by the '581 claims. Moreover, claims 49-51 further recite a still narrower dosing range of 1 to 10 mg, specific types of cancer, and a dosing frequency of twice per day, and in combination with a specifically selected additional anti-cancer agent (docetaxel and gemcitabine, in claims 50 and 51, respectively). Nothing in the '581 patent teaches these specifically claimed methods with sufficient specificity to render the claims obvious. Thus without pure hindsight, those skilled in the art would not have been motivated to optimize the dosage and administer the claimed dosage of the single compound of formula I to the patient in need thereof based on the teaching and the claims of the '581 patent. In fact, based on the animal data of 10 mg/kg/d identified in a 28-day dog study in the '581 patent, the standard calculated safe human starting dose would be 30 mg BID (see attached Rugo et al reference, page 5475, right column, second full paragraph, under the heading "Calculation of starting dose and continuous drug dosing"). However, our clinical trial study has proven that the effectivity and safety profile resulted in the unexpected dose reductions and modification to arrive at a recommended phase II dose of 5 mg BID (see attached Rugo et al reference, page 5476, right column, Table 1, under the

heading "Summary of Cohorts (N _ 36)"). The present specification as filed, page 20, table 4, reflects the 5 mg dosage as well. Thus those skilled in the art will not achieve the claimed human recommended dosage of 5 mg, which is 6 times less than the dose projected by the animal study data taught by the '571 patent.

Applicants respectfully request that the double-patenting rejection be reconsidered and withdrawn.

Conclusion

Applicants believe all pending claims are now in condition for allowance. Should there be any issues that have not been addressed to the satisfaction of the Examiner, Applicants invite the Examiner to contact the undersigned attorney.

If any fees other than those submitted herewith are due in connection with this response, including the fee for any required extension of time (for which Applicants hereby petition), please charge such fees to Deposit Account No. 16-1445.

Respectfully submitted,

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